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DUFFY, BRADLEY	

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1643	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,361	ENG ET AL.	
	Examiner	Art Unit	
	BRADLEY DUFFY	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/7/05. 12/5/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed February 7, 2008, is acknowledged and has been entered. Claim 1 has been amended. Claims 14-35 have been canceled.

2. The election with traverse filed February 7, 2008, is acknowledged and has been entered.

Applicant has elected the invention Group II, claim 10, drawn to a method for treating a patient to reduce proliferation of and/or kill target cells that express an antigen, comprising (a) administering one or more agents that cause apoptosis of the target cells; and (b) administering an Alt-2 antibody immunoreactive with said antigen, and wherein said antibody is cytotoxic to said target cells.

Claims 1-9 and 11-13 are linking claims that link the inventions of Groups I-V.

3. Claims 1-13 are pending and are under examination.

Election/Restrictions

4. Applicant's traversal of the restriction and election requirement set forth in the Office action mailed September 4, 2007, is acknowledged.

Applicant's arguments have been carefully considered but have not been found persuasive for the following reasons:

Applicant has argued, at page 4 of the response filed February 7, 2008 that, “Applicants are claiming a genus of methods, rather than a species method limited to the use of specific antibodies. The independent genus Claim 1 do not even recite any specific antibody species".

In response, the restriction requirement mailed September 4, 2007, properly identified the genus claims of the invention as linking claims. Notably, MPEP § 809 identifies two common types of linking claims, one type being genus

claims linking species claims. Furthermore, if claims to an invention are elected that are linked to other inventions by linking claims, then the linking claims will also be examined with the claims to the elected invention (see MPEP 809).

Therefore, at page 5 of the response filed February 7, 2008 it is unclear on what basis Applicant is asserting that "the burden is on the Examiner to examine the generic claims throughout their scope, together with any claims dependent thereon drawn to non-elected species or inventions" because the instant linking claims are not allowable. As set forth in MPEP § 809 only *allowable* linking claims prevent restriction between inventions that can otherwise be shown to be divisible. Accordingly, the Examiner does not have the burden of examining claims drawn to non-elected inventions in this case because the linking claims are not allowable as set forth below.

Finally, Applicant is reminded that Groups I-V are linked by linking claims 1-9 and 11-13 and that the restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application.

In conclusion, while Applicant's traversals of the restriction requirement mailed September 4, 2007 have been carefully and fully considered, for these reasons and the reasons set forth in the restriction requirement they were not found persuasive. Thus, the restriction requirement is deemed proper and therefore made FINAL.

Oath/Declaration

5. The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. § 1.67(a), along with the surcharge set forth in 37 C.F.R. § 1.16. The new oath or declaration must properly identify the application

of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See M.P.E.P. §§ 602.01 and 602.02.

The oath or declaration is defective because:

The declaration contains alterations which have not been initialed and/or dated as is required by 37 CFR 1.52(c). For example, non-initialed and/or non-dated alterations have been made to the post office addresses of the first inventor. A properly executed oath or declaration, which complies with 37 CFR 1.67(a) and identifies the application by application number and filing date, is required.

37 C.F.R. 1.52(c)(1) states:

> Any interlineation, erasure, cancellation or other alteration of the application papers filed must be made before the signing of any accompanying oath or declaration pursuant to § 1.63 referring to those application papers and should be dated and initialed or signed by the applicant on the same sheet of paper. Application papers containing alterations made after the signing of an oath or declaration referring to those application papers must be supported by a supplemental oath or declaration under § 1.67.

In this instance, because the alterations were not dated and initialed, it cannot be ascertained by whom the alterations were made or whether the accompanying declaration was signed and dated before or after the alterations were made to the declaration. Then, in accordance with M.P.E.P. § 605.04(a), where any changes made in ink in the application or oath prior to signing should be initialed and dated by the applicants prior to execution of the oath or declaration: "The Office will not consider whether noninitialed and/or nondated alterations were made before or after signing of the oath or declaration but will require a new oath or declaration."

Information Disclosure Statement

6. The references cited in the information disclosure statements filed on December 5, 2005, and January 7, 2005, have been considered.

Priority

7. Applicant's claim under 35 USC §§ 119 and/or 120 for benefit of the earlier filing date of the US Provisional Applications 60/371,802, 60/420,269 and 60/420,291 is acknowledged.

However, claims 1-13 do not properly benefit under 35 U.S.C. §§ 119 and/or 120 by the earlier filing dates of the priority documents claimed, since those claims are rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written description and a sufficiently enabling disclosure.

To receive benefit of the earlier filing date under 35 USC §§ 119 and/or 120, the later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Accordingly, the effective filing date of the claims is deemed the filing date of PCT/US03/11457, namely April 11, 2003.

Specification

8. The disclosure is objected to because of the following informalities:

a. The specification is objected to because the use of improperly demarcated trademarks has been noted in this application. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks. See MPEP § 608.01(v).

Examples of such improperly demarcated trademarks appearing in the specification are Taxol® (see numerous instances, e.g., page 6) and Histopaque® (see, e.g., page 64).

Appropriate correction is required. Each letter of a trademark should be capitalized or otherwise the trademark should be demarcated with the appropriate symbol indicating its proprietary nature (e.g., ™, ®), and accompanied by generic terminology. Applicants may identify trademarks using the "Trademark" search engine under "USPTO Search Collections" on the Internet at <http://www.uspto.gov/web/menu/search.html>.

b. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Appropriate correction is required.

Claim Objections

9. Claim 10 is objected to as being drawn to the subject matter of a non-elected invention; i.e., claim 10 is directed in the alternative to the subject matter of the non-elected inventions of Groups I and III-V.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claims 1-13 are indefinite because claim 1 is directed to a method for treating a patient to reduce proliferation of and/or kill target cells that express an antigen; yet the claim merely recites the process of (a) administering one or more agents that cause apoptosis of the target cells; and (b) administering an antibody immunoreactive with said antigen. There is no process step that clearly relates back to the purpose or objective of the claimed invention; consequently, the skilled artisan could not determine whether each and every process step

considered essential to the practice of the claimed invention has been included in the body of the claim. Thus, in the absence of a correlative step positively relating the whole of the process to its intended use, as recited in the preamble, these claims fail to delineate the subject matter that Applicant regards as the invention with the requisite degree of clarity and particularity to permit the skilled artisan to know or determine infringing and non-infringing subject matter and thereby satisfy the requirement set forth under 35 U.S.C. § 112, second paragraph.

(b) Claim 10 is vague and indefinite in the recitation "Alt-2" as the sole means of identifying the antibody or antibodies to which the claims are directed. The use of laboratory designations to identify a particular antibody renders the claims indefinite because different laboratories may use the same laboratory designations to define completely different antibodies. For example, US Patent 7,198,928 (Laing et al. 2007) discloses antibodies which bind a Cox-1 variant, designated Alt-2, and thus the use of a laboratory designation alone cannot suffice to clearly and particularly identify the antibody which is necessarily administered to the patient. Furthermore, it is noted that the specification at page 13, refers to the designation ALT-2 and presents the following disclosure in parenthesis “(OvaRex® MAb B43.13, oregovomabmurine IgG1, specifically binds to CAI CA 125; ATCC No. PTA- 1883),”. Accordingly, it is unclear is the recitation of Alt-2 is referring to one of these antibodies in particular, or if they are merely exemplary of different Alt-2 antibodies. This rejection can be overcome by amending claim 10 to specifically and uniquely identify the ALT-2 antibody, for example, by including reference to the biological deposit of a hybridoma or cell line producing the antibody, provided no new matter is added.

Accordingly, these claims are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, an of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a "written description" rejection.

The considerations that are made in determining whether a claimed invention is supported by an adequate written description are outlined by the published Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, ``Written Description'' Requirement (Federal Register; Vol. 66, No. 4, January 5, 2001; hereinafter "Guidelines"). A copy of this publication can be viewed or acquired on the Internet at the following address: <http://www.gpoaccess.gov/>.

These guidelines state that rejection of a claim for lack of written description, where the claim recites the language of an original claim should be rare. Nevertheless, these guidelines further state, "the issue of a lack of written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant has possession of the claimed invention" (*Id.* at 1105). The "Guidelines" continue:

> The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art. This problem may arise where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process.

Furthermore, the Federal Circuit has commented that each case involving the issue of written description, "must be decided on its own facts. Thus, the precedential value of cases in this area is extremely limited." *Vas-Cath*, 935 F.2d at 1562 (quoting *In re Driscoll*, 562 F.2d 1245, 1250 (C.C.P.A. 1977)). See *Noelle v. Lederman*, 69 USPQ2d 1508 (CAFC 2004).

Finally, with further regard to the proposition that, as *original* claims, the claims themselves provide *in haec verba* support themselves provide *in haec verba* support sufficient to satisfy the written description requirement, the Federal Circuit has explained that *in ipsis verbis* support for the claims in the specification does not *per se* establish compliance with the written description requirement:

> Even if a claim is supported by the specification, the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is claimed. The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). *See also:* University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 1892 (CA FC 2004).

Thus, an original claim may provide written description for itself, but it must still be an adequate written description, *which establishes that the inventor was in possession of the invention*.

In the instant case, the claims are broadly drawn to a diverse genus of processes of treating patients to reduce proliferation and/or kill target cells that express a structurally and/or functionally diverse genus of antigens comprising administering a structurally and/or functionally diverse genus of "agents that cause apoptosis of the target cells" and administering a structurally and/or functionally diverse genus of "antibodies immunoreactive with said antigen". Claim 9 is further drawn to the antibody being a "xenotypic monoclonal antibody"

and claim 10 is further drawn to the “xenotypic monoclonal antibody” being designated “ALT-2”.

However, as will be explained in further detail in the following paragraphs, in contrast to the breadth of the claims, the specification only adequately describes processes of treating ovarian cancer patients to reduce proliferation of and/or kill ovarian tumor cells expressing the CA125 antigen, comprising (a) administering to said patient the monoclonal B43.13 antibody which specifically binds CA125 and is produced by a hybridoma deposited with the ATCC under accession number PTA-1883 and (b) administering to said patient a chemotherapeutic agent or irradiation, wherein administering said antibody and said chemotherapeutic agent or irradiation reduces proliferation of and/or kills ovarian tumor cells expressing the CA125 antigen.

As a first point wherein the claims are drawn to administering a structurally and/or functionally diverse genus of “agents that cause apoptosis of the target cells" to patients, it is submitted that the specification fails to a adequately describe processes of administering this broad genus of agents to a patient because one of ordinary skill in the art could not immediately envision, recognize or predict which “agents that cause apoptosis” could be administered to patients in practicing the claimed method because it remains highly unpredictable whether any given agent that causes apoptosis could be used in the clinical setting to treat a patient. Accordingly, one of skill in the art would only reasonably conclude that Applicant was in possession of methods of administering combination therapies comprising administering chemotherapeutic agents or irradiation to patients.

Notably, the specification at page 21, sets forth that an:

> "Apoptosis inducing agent" is defined herein to induce apoptosis/programmed cell death, and include, for example, irradiation, chemotherapeutic agents or receptor ligation agents, wherein the tumor cells are induced to undergo programmed cell death. Some non-limiting examples of "chemotherapeutic agents" include (liposomal) rubicin, doxobucin, taxans, topoisomerase inhibitors, carboplatin, and cisplatin. "Irradiation" as used herein means to treat the tumor cells by using standard radiation treatment and including but not limited to ~' irradiation. "Receptor ligation" as used herein means to treat the tumor cells by using antibodies or ligands to receptors that trigger induction of apoptosis such as the receptors of the EGF receptor family or CD20.

Accordingly, the claims are broadly, but reasonably drawn to administering any of a structurally undefined genus of agents that induce apoptosis to a patient; yet as will be explained in more detail, the process of apoptosis, or programmed cell death, remains a highly complex and poorly understood process in the art of therapeutically treating patients for any given condition that would benefit from reduced proliferation and/or death of target cells, such as cancer. For example, Kim et al (Can. Bio. Ther., 5(11):1429-1442, 2006) teach that apoptosis is regulated by a highly complex extrinsic and intrinsic pathway that often undergoes mutation in cancer cells and that "cancer cells are susceptible to different types of cell death depending on the extent of acquired cellular damage" (see page 1430, left column). Furthermore, Kim et al teach that "[e]ven though apoptosis is thought to play a major role in anticancer therapy, the clinical relevance of induction of apoptosis remains uncertain, particularly in solid tumors". Accordingly, it is submitted that one of skill in the art could not immediately envision, recognize or predict the structure of the "agents that cause apoptosis" which could be used in the claimed methods to treat a patient. Notably, in support of this conclusion, Russo et al (An. Onc., 17:115-123, 2006) teach that, "[a]lthough at present there are still many components of the apoptotic pathways that are still not fully understood, the information collected so far has led to a better knowledge of the mechanisms of resistance to standard chemo and radio-therapy, as well as possible strategies aimed at restoring apoptotic sensitivity" (see pager 121, left column). Thus, while other agents that cause apoptosis that can be used in the clinic to treat certain types of cancer may be identified by screening for agents which cause apoptosis of target cells and further screening for their ability to be administered in a clinical setting, it is duly noted that the written description provision of 35 U.S.C § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for identifying it.

> The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled

> in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed*.

Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (CAFC 1991). See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993); *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.,* 18 USPQ2d 1016 (CAFC 1991); *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1892 (CAFC 2004).

Guidelines states, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (*Id.* at 1104). Moreover, because the claims are directed to a genus of agents that cause apoptosis, which vary both structurally and functionally, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. In this instance, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; Applicant has not shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; and Applicant has not described distinguishing identifying characteristics sufficient to show that Applicant was in possession of the claimed genus of agents that cause apoptosis to be administered at the time the application was filed.

Structural features that could distinguish "agents that cause apoptosis" are missing from the disclosure and the claims. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description, because specific, not general

guidance is needed. Since the disclosure does not describe the common attributes or structural characteristics that identify members of the genus, and because the genus is highly variant, the function of causing apoptosis, alone is insufficient to describe the genus of "agents" to which the claims are directed. One of skill in the art would reasonably conclude that the disclosure of methods of treating cancer patients with chemotherapeutic agents and irradiation, does not provide a representative number of species of the "agents" as encompassed by the claims.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

Secondly, wherein the claims are drawn to administering a structurally and/or functionally diverse genus of "antibodies immunoreactive with an antigen expressed by a target cell", a "xenotypic monoclonal antibody" or an antibody designated "ALT-2". it is submitted that the specification fails to a adequately describe processes of administering these broad genera of "antibodies" because one of ordinary skill in the art could not immediately envision, recognize or predict which of these "antibodies" could be administered to patients in practicing the claimed method because e.g., one of skill in the art could not immediately envision, recognize or predict the structure of the antigen expressed by the target cell. Notably, the claims do not require the "antigen" to have any particular structure and/or function and therefore, there can be no correlation of any particular identifying structural feature with any function of the claimed antibodies. Thus, the specification fails to adequately describe these antibodies, as a whole, because the skilled artisan could not immediately envision, recognize or distinguish as least most of its members from other antibodies, as the specification fails to describe its members as sharing any particularly identifying (i.e., substantial) structural feature, which correlates with any one particularly

identifying functional feature that is also shared by many, if not all, of these antibodies.

For example, it remains highly unpredictable whether any given antibody specific for a structurally undefined antigen expressed by a target cell when administered will be effective to treat a patient to reduce proliferation of and /or kill target cells that express such an antigen. As evidenced, by Scher (JNCI, 92(23):1866-1868, 2000), the Her2 antigen is known to be expressed in multiple different types of cancer that have originated in different tissue types such as breast tissue and prostate tissue. However, while the antibody trastuzumab is effective to treat a breast cancer patient to reduce proliferation of and/or kill a breast cancer cell expressing HER2, in prostate cancer patients the antibody trastuzumab does not show an objective response (see entire document, e.g., page 1866 and 1868).

To further elaborate on the reasons that the genus of antibodies is not adequately described, based on the knowledge in the art pertaining to antibody effects of cell growth, it is submitted that "an antibody immunoreactive with said antigen", "a xenotypic monoclonal antibody" or an antibody designated "Alt-2" may accelerate cell proliferation, inhibit cell proliferation or have no effect on cell proliferation. For example, it is recognized in the art that depending on the epitope bound by an antibody on the antigen expressed by tumor cells that some naked antibodies will inhibit tumor growth while some naked antibodies actually accelerate tumor growth (see e.g., Stancovski et al (PNAS, 88: 8691-8695, 1991 (page 8693, column 1)). While the reason that the naked antibody may be ineffective is not known, Jiang et al. (*J. Biol. Chem.* 2005 Feb 11; **280** (6): 4656-4662), for example, teaches that it is well known that different biological effects are associated with epitope specificity of the antibodies (see entire document, particularly page 4656, column 2). Notably, while the instant specification teaches a monoclonal antibody B43.13 which specifically binds the ovarian tumor antigen CA125 which is produced by a hybridoma with the Accession number ATCC No. PTA-1883 that can inhibit cell proliferation of ovarian cells expressing

the CA125 antigen, and while the specification uses the indicates that this B43.13 antibody may be exemplary of an “Alt-2" antibody, the specification is broadly, but reasonably interpreted to include a structurally and functionally diverse genus of antibodies in the Alt-2 genus because of the following disclosure at page 13, wherein it appears that other structurally and functionally diverse antibodies exemplify an “Alt-2” antibody as well:

“Alt-2 (OvaRex® MAb B43.13, oregovomabmurine IgG1, specifically binds to CAI CA 125; ATCC No. PTA- 1883)”.

Accordingly, while the term “Alt-2” is also indefinite for the reasons detailed in the above rejection of the claims’ under 35 USC 112, second paragraph, it appears that the specification broadly encompasses murine monoclonal IgG1 antibodies as well as other antibodies that bind the CA 125 antigen in this genus. However, for the reasons detailed above, one of skill in the art could not immediately envision, recognize or identify which of the antibodies designated “Alt-2” would be effective in the claimed methods, because depending on the antigen or epitope on the antigen that the “Alt-2” antibody binds, the antibody could accelerate cell proliferation, inhibit cell proliferation or have no effect on cell proliferation. For these reasons, one of skill in the art could not immediately envision, recognize or identify the structure of the antibodies which would be effective in the claimed methods and therefore, one of skill in the art would not recognize that Applicant was in possession of the claimed methods.

For these reasons, as a whole, it is submitted that the specification would amount to no more than a mere invitation to the skilled artisan to *discover* the identity of other processes of treating patients to reduce proliferation and/or kill target cells that express a structurally and/or functionally diverse genus of antigens comprising administering a structurally and/or functionally diverse genus of “agents that cause apoptosis of the target cells" and administering a structurally and/or functionally diverse genus of “antibodies immunoreactive with said antigen” or “xenotypic monoclonal antibodies” or “ALT-2 antibodies” as

encompassed by the claims; it is duly noted that the written description provision of 35 U.S.C § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for identifying it.

Once again, given the lack of particularity with which the diverse genus of processes of treating patients to reduce proliferation and/or kill target cells that express a structurally and/or functionally diverse genus of antigens comprising administering a structurally and/or functionally diverse genus of "agents that cause apoptosis of the target cells" and administering a structurally and/or functionally diverse genus of "antibodies immunoreactive with said antigen", to which the claims are directed, are described in the specification, it is submitted that the skilled artisan could not immediately envision, recognize or distinguish at least most of the methods encompassed by this genus; and therefore the specification would not reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed.

14. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, **while being enabling for using** methods encompassed by the claims that are disclosed by the prior art, **does not reasonably provide enablement for using** processes of treating patients to reduce proliferation and/or kill target cells that express an antigen comprising administering agents that cause apoptosis of the target cells and administering an antibody immunoreactive with said antigen, or wherein the antibody is a xenotypic monoclonal antibody or wherein the antibody is designated "ALT-2". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are herein drawn to processes of treating patients to reduce proliferation and/or kill target cells that express an antigen comprising administering one or more agents that cause apoptosis of the target cells and

administering an antibody immunoreactive with said antigen. Claim 9 is further drawn to the antibody being a "xenotypic monoclonal antibody" and claim 10 is further drawn to the "xenotypic monoclonal antibody" being designated "ALT-2"

The amount of guidance, direction, and exemplification disclosed in the specification, as filed, would not be sufficient to enable the skilled artisan to use the claimed invention at the time the application was filed without undue experimentation.

MPEP § 2164.01 states:

> The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors, which have been outlined in the Federal Circuit decision of *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), include, but are not limited to, the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed. See also *Ex parte Forman*, 230 USPQ 546 (BPAI 1986).

For the reasons set forth in the above rejection of the claims, as failing to satisfy the written description requirement, it has been submitted that the specification would amount to no more than an invitation to the skilled artisan to discover the identity of other processes encompassed by the claims.

Applicant is reminded reasonable correlation must exist between the scope of the claims and scope of enablement set forth.

In deciding *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970), the Court indicated the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. "Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." *Genentech Inc. v. Novo Nordisk A/S*, 42 USPQ2d 1001, 1005 (CA FC 1997).

As explained in the above rejection of the claims, as failing to satisfy the written description requirement, because the claims are directed to processes of using a genus of "agents that cause apoptosis" and "antibodies immunoreactive to an antigen expressed on a target cell", "xenotypic monoclonal antibodies" or "antibodies designated "ALT-2" that have not been described so as to permit the skilled artisan to immediately envision, recognize or distinguish the members of these genera, the skilled artisan could not make these "agents" or "antibodies" without undue and/or unreasonable experimentation; and if these "agents" or "antibodies" cannot be made without undue and/or unreasonable experimentation, the specification would not reasonably enable the skilled artisan to use the claimed processes without undue experimentation.

Furthermore, as evidenced by Scher, Russo et al, Kim et al and Stancovski et al (all supra), in the above rejection of the claims as lacking adequate written description, those of skill in the art also recognize the unpredictability of treating patients to reduce proliferation of and/or kill target cells that express an antigen, and in particular using an agent that causes apoptosis of a target cell and antibodies that are specific for an antigen expressed by the tumor cells in combination. By way of further explanation, as evidenced by Stancovski et, antibodies immunoreactive with an antigen expressed on a target cell can accelerate cell proliferation or inhibit cell proliferation. Accordingly, it is

submitted that it is highly unpredictable whether these merely prophetic agents or antibodies can be used in the claimed methods without undue experimentation. For example, one of skill in the art would be subject to undue experimentation to practice the claimed methods to reduce proliferation of target cells if the antibody administered accelerates cell proliferation.

To further elaborate on the art-recognized unpredictability in treating e.g., patients with cancer, Jain (Scientific American, 271(1):58-65, July 1994) discloses that there are many art known barriers to the delivery of drugs to treat patients with cancer. These impediments include (1) Non-uniform blood delivery to all areas of the tumor in which some areas of the tumor receive therapeutic agents and other areas of the tumor receive no therapeutic agent at all. (Page 60 col. 3); (2) Increased viscosity of blood in the tumor itself which also hinders drug delivery to the tumor (see paragraph bridging pages 60 and 61); (3) High liquid pressures in the interstitial matrix can retard the delivery of large therapeutic agents, such as antibodies, into tumors (page 61, Col. 1 paragraph 1); (4) Convection is a necessary mechanism by which larger therapeutic molecules such as antibodies, reach target cells which are not directly fed by the vasculature. Convection is not observed in large tumors (defined as more than ½ centimeter in diameter, page 62 col. 1) and convection is necessary for adequate drug delivery of molecules having a molecular weight of more than 5000 (page 61, col. 1 through page 63, col. 3) and (4) Molecules as large as antibodies (i.e., MW=150,000) would require several months to reach a uniform concentration in a tumor that measures 1 centimeter in radius (page 63, col. 2). Furthermore, with particular regard for using antibodies to treat cancer, Dillman, (Annals of Internal Medicine, 111:592-603, 1989) summarizes (see abstract) the status of in-vivo use of monoclonal antibodies for treating cancer wherein despite advances in biotechnology, many major hurdles persist including tumor cell heterogeneity, lack of cytotoxicity, and the development of human anti-mouse antibodies (HAMA). Also, Weiner (Seminars in Oncology, 26 (4 Suppl 12):41-50, August 1999) provided an overview of monoclonal antibody therapy including

some promising activity, however, major obstacles to clinical efficacy still exist extending the unpredictability of this treatment. This includes impaired distribution and delivery of antibody to the tumor site, inadequate trafficking of potential cellular effectors to tumor, antigenic heterogeneity, shed or internalized targets and insufficient target specificity (see page 43). Therefore, in view of the evidence of the lack of the predictability of the art to which the invention pertains, it is submitted that one of skill in the art would be subject to undue experimentation to practice the claimed methods which comprise administering any agent that causes apoptosis and any antibody to an antigen expressed on any target cell to treat any patient comprising any target cell.

Once again, Applicant is reminded that reasonable correlation must exist between the scope of the claims and scope of enablement set forth.

Thus, the overly broad scope of the claims would merely serve as an invitation to one skilled in the art to identify other processes of treating a patient that are encompassed by the claims.

In conclusion, upon careful consideration of the factors used to determine whether undue experimentation is required, in accordance with the Federal Circuit decision of *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the amount of guidance, direction, and exemplification disclosed in the specification, as filed, is not deemed sufficient to have enable the skilled artisan to use the claimed invention at the time the application was filed without undue and/or unreasonable experimentation.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1-9 and 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by DeNardo et al (PNAS, 94:4000-4004, 1997).

The claims are herein drawn to methods comprising administering one or more agents that cause apoptosis of tumor cells (see claim 3) expressing an antigen, wherein the agent that causes apoptosis of the target cells is a chemotherapeutic agent(see claim 8), such as paclitaxel (tradename Taxol®) (see page 29 of the instant specification which describes paclitaxel as a chemotherapeutic agent) and administering an antibody immunoreactive with said antigen. The claims are further drawn to administering said agent and said antibody conjointly (see claim 5), said agent prior to said antibody (see claim 6) or said antibody prior to said agent (see claim 7). Claim 9 is further drawn to the antibody being a xenotypic monoclonal antibody.

While the phrase "xenotypic monoclonal antibody" is not expressly defined in the specification, it is being interpreted in light of the disclosure at page 26 that

"Binding agents of the present invention are capable of inducing a host anti-xenotypic antibody (HAXA) response"

and the disclosure at page 12 that,

"The term "antibody" as used herein, unless indicated otherwise, is used broadly to refer to both antibody molecules and a variety of antibody-derived molecules".

Furthermore, since it is commonly known in the art that any antibody is capable of inducing a host anti-xenotypic antibody (HAXA) response, when injected into a species that does not recognize that antibody as a self-antigen, the term "xenotypic monoclonal antibody" is broadly, but reasonably interpreted to include any monoclonal antibody.

DeNardo et al teach methods comprising administering paclitaxel and administering the murine-human monoclonal antibody ChL6, which is immunoreactive with an integral membrane glycoprotein highly expressed on human breast carcinomas, conjugated to the radioisotope ^{90}Y, to a murine xenograft model of human breast cancer (see entire document, e.g., abstract and

Table 1). DeNardo et al further teach administering paclitaxel and the antibody conjugate together at the same time, which absent a showing otherwise is considered conjointly, and in either order to test the therapeutic effect of these different combinations of therapy (see e.g., abstract and page 4003). Finally, DeNardo et al teach that this combination therapy resulted in dramatic tumor regression, i.e. a reduction in the number of tumor cells, in the mouse xenograft model of human breast cancer (see e.g., page 4003, left column).

Notably, while DeNardo et al do not expressly teach that their methods elicit an effective B and/or T cell response as recited in claims 11 and 12, it is noted that the specification teaches at page 15 that “an effective immune response is an effective B and/or T cell response” and sets forth that “An "effective immune response" is defined herein wherein the patient experiences partial or total alleviation or reduction of signs or symptoms of illness, and specifically includes, without limitation, prolongation of survival”.

Accordingly, since DeNardo et al teach that their methods result in dramatic tumor regression, which would be considered a “reduction of signs or symptoms of illness” the methods of DeNardo et al appear materially and manipulatively indistinguishable from the claimed processes. Therefore, absent a showing of any difference, DeNardo et al is deemed to anticipate the claimed invention.

17. Claims 1-9 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Slamon et al (NEJM, 344(11):783-792, 2001, of record).

The claims are herein drawn to methods comprising administering one or more agents that cause apoptosis of tumor cells (see claim 3) expressing an antigen, wherein the agent that causes apoptosis of the target cells is a chemotherapeutic agent(see claim 8), such as paclitaxel (tradename Taxol®) (see page 29 of the instant specification which describes paclitaxel as a chemotherapeutic agent) and administering an antibody immunoreactive with said antigen. The claims are further drawn to administering said agent and said

antibody conjointly (see claim 5), said agent prior to said antibody (see claim 6) or said antibody prior to said agent (see claim 7) While, Claim 9 is further drawn to the antibody being a xenotypic monoclonal antibody, for the reasons set forth above, a "xenotypic monoclonal antibody", is broadly, but reasonably interpreted to include any monoclonal antibody. Claim 13 is further drawn to the patient being a human.

In this case, since the specification does not expressly define the term "conjointly", it is being interpreted to include methods of administering the agent and antibody in combination with each other, but not necessarily at the same time. Notably, Merriam-Webster's Online Dictionary, 10th Edition (copyright © 2005 by Merriam-Webster, Inc.), which is available on the Internet at <http://www.m-w.com/>, defines the term "conjoint" as "related to, made up of, or carried on by two or more in combination".

Slamon et al teach methods, wherein the patient is a human, comprising administering paclitaxel and administering the murine-human monoclonal antibody trastuzumab, which is immunoreactive with the HER2 antigen highly expressed on human breast carcinomas (see entire document, e.g., abstract and page 784) . Slamon et al further teach administering paclitaxel and trastuzumab in multiple doses, such as paclitaxel once every three weeks and trastuzumab once a week (see e.g., page 784, left column) so Slamon et al teach methods that administer paclitaxel both prior to and after trastuzumab is administered. Furthermore, as explained above, since the methods of Salmon et al teach methods of administering paclitaxel and trastuzumab in combination, which would reasonably be interpreted to be "carried on by two or more in combination", absent a showing otherwise, Slamon et al is deemed to teach conjoint administration. Finally, Slamon et al teach that this combination therapy resulted in a longer time to disease progression, a higher rate of objective response, a longer duration of response, a lower rate of death at one year, longer survival, and a 20 percent reduction in the risk of death (see e.g., abstract).

Notably, while Slamon et al do not expressly teach that their methods elicit an effective B and/or T cell response as recited in claims 11 and 12, it is noted that the specification teaches at page 15 that “an effective immune response is an effective B and/or T cell response” and sets forth that “An "effective immune response" is defined herein wherein the patient experiences partial or total alleviation or reduction of signs or symptoms of illness, and specifically includes, without limitation, prolongation of survival”.

Accordingly, since Slamon et al expressly teach that their methods result in prolongation of survival, the methods of Slamon et al appear materially and manipulatively indistinguishable from the claimed processes. Therefore, absent a showing of any difference, Slamon et al is deemed to anticipate the claimed invention.

18. Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 6,241,985 (Madiyalakan et al, 2001) as evidenced by US Patent 6,358,976 (Wityak et al, 2002).

The claims are herein drawn to methods comprising administering one or more agents that cause apoptosis of tumor cells (see claim 3) expressing an antigen, wherein the agent that causes apoptosis of the target cells is a chemotherapeutic agent (see claim 8), and administering an Alt-2 antibody, such as a B43.13 antibody (see page 13 of the specification which describes a B43.13 antibody as an Alt-2 antibody) immunoreactive with said antigen. The claims are further drawn to administering said agent and said antibody conjointly (see claim 5), said agent prior to said antibody (see claim 6) or said antibody prior to said agent (see claim 7) While, Claim 9 is further drawn to the antibody being a xenotypic monoclonal antibody, for the reasons set forth above, a “xenotypic monoclonal antibody”, is broadly, but reasonably interpreted to include any monoclonal antibody. Claim 13 is further drawn to the patient being a human.

As evidenced by US Patent 6,358,976, combination treatment is commonly known in the art to include administering two therapies concurrently or sequentially in any order (see column 57).

US Patent 6,241,985 teaches methods, wherein the patient is a human, comprising administering a B43.13 antibody produced by a hybridoma deposited with the ATCC under accession number PTA-1883, which is immunoreactive with a CA125 antigen highly expressed on ovarian carcinomas alone or in combination with chemotherapeutic agents (see entire document, e.g., claims 1-14 and columns 13, 14 and 15). Notably, since combination therapy would be understood to include concurrent concurrently or sequential administration in any order, the methods of US Patent 6,241,985, absent a showing otherwise, are materially and manipulatively indistinguishable from the instantly claimed methods. US Patent 6,241,985 further teaches that the injection of B43.13 antibody to patients containing elevated levels of CA125 leads to antigen specific humoral and cellular response which in turn leads to tumor killing followed by improved survival (see e.g., column 19).

Accordingly, since US Patent 6,241,985 expressly teaches that injection of B43.13 antibody results in an antigen specific humoral and cellular response, which would comprise the B cell and T cell responses of claims 11 and 12, the methods of US Patent 6,241,985 appear materially and manipulatively indistinguishable from the claimed processes. Furthermore, since US Patent 6,241,985 teaches that injection of B43.13 antibody results in prolongation of survival, which as set forth in the instant specification would be considered an effective B cell and/or T cell response of claims 11 and 12, the methods of US Patent 6,241,985 appear materially and manipulatively indistinguishable from the claimed processes for this reason as well. Therefore, absent a showing of any difference, US Patent 6,241,985 is deemed to anticipate the claimed invention.

Double Patenting

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. Claims 1-13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of US Patent No. 6,241,985 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

The instant claims are described supra.

Claims 1-14 of US Patent No. 6241985 B1 are herein drawn to methods comprising contacting the CA125 antigen present in the host with a composition comprising the murine monoclonal antibody B43.13 that specifically binds to an epitope on said antigen wherein a host immune response is elicited.

In this case, while the methods in the instant application are more specific than the more generic methods set forth in US Patent No. 6241985 B1 because they do not recite administering a chemotherapeutic agent along with the Alt-2 antibody, the instantly claimed methods appear to be obvious variants of Claims 1-14 of US Patent No. 6241985 B1. Notably, for example, the specification of US Patent No. 6241985 B1 specifically exemplifies administering a B43.13 monoclonal antibody, which as detailed above is exemplified as an Alt-2 antibody specific for the CA125 antigen expressed in ovarian cancer in the instant specification, to human patients at e.g., columns 15 and 19, and specifically exemplifies that the methods of the invention can also comprise administering a chemotherapeutic agent in combination with the antibody at column 14.

Notably, MPEP § 804.II.B.1 states that when considering obviousness-type double patenting issues, the disclosure of the patent [or copending application] cannot be used as prior art, but "[t]his does not mean one is precluded from all use of the patent disclosure". MPEP § 804.II.B.1 continues, "[t]he specification can always be used as a dictionary to learn the meaning of a term in the patent [or application] claim". Citing *In re Vogel and Vogel*, 164 USPQ 619 (CCPA 1970), MPEP § 804.II.B.1 states, "one must first 'determine how much of the patent [or application] disclosure pertains to the invention claimed in the patent [or application]' because only '[t]his portion of the specification supports the patent claims and may be considered' " and " 'this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, **since only the disclosure of the invention claimed in the patent may be examined**"

[emphasis added]. Consistently, in this instance, the examiner used only that portion of the patent disclosure that pertains to the claimed invention.

Further addressing *In re Vogel and Vogel*, the Court decided the correctness of the conclusion that a patent claim drawn to a process for packaging "pork" would be obvious over a pending claim drawn to a process for packaging "meat", since although "pork does not read on "meat", "meat" reads literally on "pork". However, the Court further noted "viewing the inventions in reverse order, i.e., as though the broader claims issued first, does not reveal that the narrower (pork) process is in any way unobvious over the broader (meat) invention disclosed and claimed in the instant application" *Id.* at 623. The examiner believes this is because, were the patent claim to broadly recite "meat", although "pork" does not read on "meat" (i.e., a species encompassed by the genus generally does not suffice to describe the genus), the specification states how the claimed process is to be carried out with "pork". The Court indicated that this portion of the specification, stating how the claimed process is to be carried out using pork, supports the patent claims *and may be considered*. *Id.* at 622.

In certain situations, the supporting disclosure may be used to define terms in a claim and to determine whether the invention claimed has been modified in an obvious or unobvious manner. See *Carman Industries, Inc. v. Wahl et al.*, 220 USPQ 481 (CA FC 1983). If modified in an unobvious manner, there is no double patenting issue. In this instance, there can be no mistake that the invention claimed in the instant application is an obvious "variant" of the invention claimed in the patent, because the supporting disclosure of the latter teaches methods of combining chemotherapeutic agents and antibodies for administration to patients as instantly recited in claims.

If the instant claims were drawn instead to an unobvious "variant", or to an invention that might only be gleaned from consideration of portions of the disclosure that do not support the patented claims, such that the consideration would be improper, then there would be no double patenting issue. Because only those portions of the disclosure that support the copending claims has been

considered, and those portions include a description of the "variant" claimed in the instant application, then a double patenting rejection is believed warranted.

Accordingly, it is submitted that the subject matter claimed in the instant application would be seen as an obvious variation of the subject matter claimed in the copending application.

21. Claims 1-13 are directed to an invention not patentably distinct from claims 1-14 of US Patent No. 6241985 B1. Specifically, although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons set forth in the above rejection of the claims on the ground of nonstatutory obviousness-type double patenting.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned US Patent No. 6241985 B1, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

22. Claims 1-13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 24-27, 44-47 and 68-76

of US Patent No. 7318921 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

The instant claims are described *supra*.

Claims 1-7, 24-27, 44-47 and 68-76 of US Patent No. 7318921 B2 are herein drawn to methods comprising contacting in vivo the CA 125 antigen present in a host's serum with a composition comprising the B43.13 monoclonal antibody that specifically binds to an epitope on said antigen, whereby an effective immune is elicited.

In this case, while the methods in the instant application are more specific than the more generic methods set forth in US Patent No. 7318921 B2 because they do not recite administering a chemotherapeutic agent along with the Alt-2 antibody, the instantly claimed methods appear to be obvious variants of Claims 1-7, 24-27, 44-47 and 68-76 of US Patent 7318921 B2. Notably, for example, the specification of US Patent No. 7318921 B2 specifically exemplifies administering a B43.13 monoclonal antibody, which as detailed above is exemplified as an Alt-2 antibody specific for the CA125 antigen expressed in ovarian cancer in the instant specification, to human patients at e.g., columns 27 and 44, and specifically exemplifies that the methods of the invention can also comprise administering a chemotherapeutic agent in combination with the antibody at column 26.

In this instance, it is submitted that there can be no mistake that the invention claimed in the instant application is an obvious “variant” of the invention claimed in the patent, because the supporting disclosure of the latter teaches methods of combining chemotherapeutic agents and antibodies for administration to patients as instantly recited in the claims.

If the instant claims were drawn instead to an unobvious “variant”, or to an invention that might only be gleaned from consideration of portions of the disclosure that do not support the copending claims, such that the consideration would be improper, then there would be no double patenting issue. Because only those portions of the disclosure that support the patented claims has been

considered, and those portions include a description of the "variant" claimed in the instant application, then a double patenting rejection is believed warranted.

Accordingly, it is submitted that the subject matter claimed in the instant application would be seen as an obvious variation of the subject matter claimed in the patent.

23. Claims 1-13 are directed to an invention not patentably distinct from claims 1-7, 24-27, 44-47 and 68-76 of US Patent No. 7318921 B2. Specifically, although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons set forth in the above rejection of the claims on the ground of nonstatutory obviousness-type double patenting.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned US Patent No. 7318921 B2, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

24. Claims 1-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 22-

28, 37-38 and 45-46 of copending Application No. 10/831,886. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

The instant claims are described supra.

Claims 1-7, 22-28, 37-38 and 45-46 of copending Application No. 10/831,886 are herein drawn to methods comprising administering concurrently, or in either order, an Alt-2 antibody and a chemotherapeutic drug to a human patient suffering from cancer, wherein the antigen expressed by the tumor cells is CA125 to generate an effective host immune response.

Accordingly, it is submitted that the methods of copending Application No. 10/831,886 comprise manipulatively and materially indistinguishable method steps which elicit an effective host immune response that is an effective T cell or B cell response as instantly recited.

For this reason, the claimed inventions are so substantially similar that for the most part, the claimed subject matter of copending Application No. 10/831,886 anticipates the claimed subject matter of the instant application and any minor differences in the subject matter claimed in the instant application would be seen as an obvious variation of the subject matter claimed in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

25. Claims 1-13 are directed to an invention not patentably distinct from claims 1-7, 22-28, 37-38 and 45-46 of copending Application No. 10/831,886. Specifically, although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons set forth in the above provisional rejection of the claims on the ground of nonstatutory obviousness-type double patenting.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common

ownership (see MPEP Chapter 2300). Commonly assigned copending Application No. 10/831,886, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

26. Claims 1-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 6-12 and 14-15 of copending Application Nos. 11/472,808, 11/981714 and 11/981,732. Currently, claims 1-3, 6-12 and 14-15 of these three copending applications are word-for-word identical. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

The instant claims are described supra.

Claims 1-3, 6-12 and 14-15 of copending Application Nos. 11/472,808, 11/981714 and 11/981,732 are herein drawn to methods comprising contacting a CA125 antigen in vivo with a monoclonal antibody to elicit a host cellular and/or humoral immune response.

In this case, while the methods in the instant application are more specific than the more generic methods set forth in copending Application Nos. 11/472,808, 11/981714 and 11/981,732 because they do not recite administering

a chemotherapeutic agent along with an Alt-2 antibody, the instantly claimed methods appear to be obvious variants of Claims 1-3, 6-12 and 14-15 of copending Application No. 11/472,808. As a first point, methods of contacting CA125 in vivo would require administering the antibody to a patient. Secondly, for example, the specification of copending Application Nos. 11/472,808, 11/981714 and 11/981,732 all have disclosures that specifically exemplify administering a B43.13 monoclonal antibody, which as detailed above is exemplified as an Alt-2 antibody specific for the CA125 antigen expressed in ovarian cancer in the instant specification, to human patients at e.g., pages 24 and 29, and all specifically exemplify that the methods of the invention can also comprise administering a chemotherapeutic agent in combination with the antibody at page 23.

Notably, MPEP § 804.II.B.1 states that when considering obviousness-type double patenting issues, the disclosure of the patent [or copending application] cannot be used as prior art, but "[t]his does not mean one is precluded from all use of the patent disclosure". MPEP § 804.II.B.1 continues, "[t]he specification can always be used as a dictionary to learn the meaning of a term in the patent [or application] claim". Citing *In re Vogel and Vogel*, 164 USPQ 619 (CCPA 1970), MPEP § 804.II.B.1 states, "one must first 'determine how much of the patent [or application] disclosure pertains to the invention claimed in the patent [or application]' because only '[t]his portion of the specification supports the patent claims and may be considered' " and " 'this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, **since only the disclosure of the invention claimed in the patent may be examined**" [emphasis added]. Consistently, in this instance, the examiner used only that portion of the copending application disclosure that pertains to the claimed invention.

Further addressing *In re Vogel and Vogel*, the Court decided the correctness of the conclusion that a patent claim drawn to a process for

packaging "pork" would be obvious over a pending claim drawn to a process for packaging "meat", since although "pork does not read on "meat", "meat" reads literally on "pork". However, the Court further noted "viewing the inventions in reverse order, i.e., as though the broader claims issued first, does not reveal that the narrower (pork) process is in any way unobvious over the broader (meat) invention disclosed and claimed in the instant application" *Id.* at 623. The examiner believes this is because, were the patent claim to broadly recite "meat", although "pork" does not read on "meat" (i.e., a species encompassed by the genus generally does not suffice to describe the genus), the specification states how the claimed process is to be carried out with "pork". The Court indicated that this portion of the specification, stating how the claimed process is to be carried out using pork, supports the patent claims *and may be considered*. *Id.* at 622.

In certain situations, the supporting disclosure may be used to define terms in a claim and to determine whether the invention claimed has been modified in an obvious or unobvious manner. See *Carman Industries, Inc. v. Wahl et al.*, 220 USPQ 481 (CA FC 1983). If modified in an unobvious manner, there is no double patenting issue. In this instance, there can be no mistake that the invention claimed in the instant application is an obvious "variant" of the invention claimed in the copending application, because the supporting disclosure of the latter teaches methods of combining chemotherapeutic agents and antibodies for administration to patients as instantly recited in the claims.

If the instant claims were drawn instead to an unobvious "variant", or to an invention that might only be gleaned from consideration of portions of the disclosure that do not support the copending claims, such that the consideration would be improper, then there would be no double patenting issue. Because only those portions of the disclosure that support the copending claims has been considered, and those portions include a description of the "variant" claimed in the instant application, then a double patenting rejection is believed warranted.

Accordingly, it is submitted that the subject matter claimed in the instant application would be seen as an obvious variation of the subject matter claimed in the copending application.

27. Claims 1-13 are directed to an invention not patentably distinct from claims 1-3, 6-12 and 14-15 of copending Application Nos. 11/472,808, 11/981714 and 11/981,732. Specifically, although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons set forth in the above provisional rejection of the claims on the ground of nonstatutory obviousness-type double patenting.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned copending Application Nos. 11/472,808, 11/981714 and 11/981,732, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

28. Claims 1-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 192-197,

199-201 and 205-214 of copending Application No. 11/607,803. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

The instant claims are described supra.

Claims 192-201 and 205-214 of copending Application No. 11/607,803 are herein drawn to methods comprising contacting the CA125 antigen present in the host's serum with a composition comprising the an antibody specific for CA125 whereby an effective host immune response is elicited.

In this case, while the methods in the instant application are more specific than the more generic methods set forth in copending Application No. 11/607,803 because they do not recite administering a chemotherapeutic agent along with an Alt-2 antibody, the instantly claimed methods appear to be obvious variants of Claims 192-201 and 205-214 of copending Application No. 11/607,803. Notably, for example, the specification of copending Application No. 11/607,803 specifically exemplifies administering a B43.13 monoclonal antibody, which as detailed above is exemplified as an Alt-2 antibody specific for the CA125 antigen expressed in ovarian cancer in the instant specification, to human patients at e.g., pages 43 and 55, i.e., contacting the CA125 antigen present in the host's serum with a composition comprising the an antibody specific for CA125. Furthermore, the specification also specifically exemplifies that the methods of the invention can also comprise administering a chemotherapeutic agent in combination with the antibody at page 42.

In this instance, it is submitted that there can be no mistake that the invention claimed in the instant application is an obvious "variant" of the invention claimed in the copending application, because the supporting disclosure of the latter teaches methods of combining chemotherapeutic agents and antibodies for administration to patients as instantly recited in the claims.

If the instant claims were drawn instead to an unobvious "variant", or to an invention that might only be gleaned from consideration of portions of the disclosure that do not support the copending claims, such that the consideration

would be improper, then there would be no double patenting issue. Because only those portions of the disclosure that support the copending claims has been considered, and those portions include a description of the "variant" claimed in the instant application, then a double patenting rejection is believed warranted.

Accordingly, it is submitted that the subject matter claimed in the instant application would be seen as an obvious variation of the subject matter claimed in the copending application.

29. Claims 1-13 are directed to an invention not patentably distinct from claims 192-197, 199-201 and 205-214 of copending Application No. 11/607,803. Specifically, although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons set forth in the above provisional rejection of the claims on the ground of nonstatutory obviousness-type double patenting.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned copending Application No. 11/607,803, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

30. Claims 1-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 18, 23, 28 and 43 of copending Application No. 11/981,644. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

The instant claims are described supra

Claims 1, 18, 23, 28 and 43 of copending Application No. 11/981,644 are herein drawn to methods comprising contacting a multi-epitopic in vivo antigen with a composition comprising a binding agent that specifically binds to an epitope on the antigen, whereby a host immune response is elicited.

In this case, while the methods in the instant application are more specific than the more generic methods set forth in copending Application No. 11/981,644 because they do not recite administering a chemotherapeutic agent along with an Alt-2 antibody, the instantly claimed methods appear to be obvious variants of Claims 1, 18, 23, 28 and 43 of copending Application No. 11/981,644. Notably, for example, the specification of copending Application No. 11/981,644 specifically exemplifies administering a B43.13 monoclonal antibody, which as detailed above is exemplified as an Alt-2 antibody specific for the CA125 antigen expressed in ovarian cancer in the instant specification, to human patients at e.g., pages 43 and 55, i.e., contacting a multi-epitopic in vivo antigen with a composition comprising a binding agent that specifically binds to an epitope on said antigen. Furthermore, the specification also specifically exemplifies that the methods of the invention can also comprise administering a chemotherapeutic agent in combination with the antibody at page 42.

In this instance, it is submitted that there can be no mistake that the invention claimed in the instant application is an obvious “variant” of the invention claimed in the copending application, because the supporting disclosure of the latter teaches methods of combining chemotherapeutic agents and antibodies for administration to patients as instantly recited in the claims.

If the instant claims were drawn instead to an unobvious "variant", or to an invention that might only be gleaned from consideration of portions of the disclosure that do not support the copending claims, such that the consideration would be improper, then there would be no double patenting issue. Because only those portions of the disclosure that support the copending claims has been considered, and those portions include a description of the "variant" claimed in the instant application, then a double patenting rejection is believed warranted.

Accordingly, it is submitted that the subject matter claimed in the instant application would be seen as an obvious variation of the subject matter claimed in the copending application.

31. Claims 1-13 are directed to an invention not patentably distinct from 1, 18, 23, 28 and 43 of copending Application No. 11/981,644. Specifically, although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons set forth in the above provisional rejection of the claims on the ground of nonstatutory obviousness-type double patenting.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned copending Applications No. 11/981,644, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C.

102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

32. Claims 1-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 18 and 23 of copending Application No. 11/982,366. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

The instant claims are described supra.

Claims 1, 18 and 23 of copending Application No. 11/982,366 are herein drawn to methods comprising contacting a multi-epitopic in vivo antigen with a composition comprising a binding agent that specifically binds to an epitope on the antigen, whereby a host immune response is elicited.

In this case, while the methods in the instant application are more specific than the more generic methods set forth in copending Application No. 11/982,366 because they do not recite administering a chemotherapeutic agent along with an Alt-2 antibody, the instantly claimed methods appear to be obvious variants of Claims 1, 18 and 23 of copending Application No. 11/982,366. Notably, for example, the specification of copending Application No. 11/982,366 specifically exemplifies administering a B43.13 monoclonal antibody, which as detailed above is exemplified as an Alt-2 antibody specific for the CA125 antigen expressed in ovarian cancer in the instant specification, to human patients at e.g., pages 43 and 55, i.e., contacting a multi-epitopic in vivo antigen with a composition comprising a binding agent that specifically binds to an epitope on said antigen. Furthermore, the specification also specifically exemplifies that the methods of the invention can also comprise administering a chemotherapeutic agent in combination with the antibody at page 42.

In this instance, it is submitted that there can be no mistake that the invention claimed in the instant application is an obvious “variant” of the invention claimed in the copending application, because the supporting disclosure of the

latter teaches methods of combining chemotherapeutic agents and antibodies for administration to patients as instantly recited in the claims.

If the instant claims were drawn instead to an unobvious "variant", or to an invention that might only be gleaned from consideration of portions of the disclosure that do not support the copending claims, such that the consideration would be improper, then there would be no double patenting issue. Because only those portions of the disclosure that support the copending claims has been considered, and those portions include a description of the "variant" claimed in the instant application, then a double patenting rejection is believed warranted.

Accordingly, it is submitted that the subject matter claimed in the instant application would be seen as an obvious variation of the subject matter claimed in the copending application.

33. Claims 1-13 are directed to an invention not patentably distinct from 1, 18 and 23 of copending Application No. 11/982,366. Specifically, although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons set forth in the above provisional rejection of the claims on the ground of nonstatutory obviousness-type double patenting.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned copending Applications No. 11/982,366, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Conclusion

34. No claims are allowed.

35. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 20050063976 A1 (Schultes et al, published 2005) teach methods of administering a B43.13 antibody to ovarian cancer patients and methods of administering the B43.13 antibody in combination with a chemotherapeutic agent.

36. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached on Monday through Friday 7:00 AM to 4:30 PM, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached at (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-

free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Respectfully,
Brad Duffy
571-272-9935

/Stephen L. Rawlings/
Primary Examiner, Art Unit 1643

/bd/
Examiner, Art Unit 1643
June 1, 2008